REMARKS

Amendments to the Claims

The amendments to the claims add no new matter. Claim 8 has been amended to add the limitations of original claim 1. Claims 11 – 18 have been deleted. New claim 19 adds no new matter, since it merely claims the product produced according to claim 8.

Rejections under 35 U.S.C. §112

Claims 2 – 10 and 12 – 18 stand rejected under 35 U.S.C. §112 as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 11 – 18 have been canceled. Claim 8 has been amended to overcome this rejection by deletion of the word "the" in three places. Claims 2 – 7 and 9 – 10 were rejected only because of their dependency from claim 8. It is respectfully requested that this rejection be withdrawn.

Rejections under 35 U.S.C. §102 and §103

The amendments to the claims overcome all of the rejections under 35 U.S.C. §102 and §103.

1. Claims 2, 5 – 8, 11 – 14, and 17 – 18 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Tsuboi et al. (EP 0 564 945, also published as US 6,063,393).

Claims 11 – 18 have been canceled.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."[1]

Tsuboi "relates to a process for the treatment of individual plants with solid shaped

[1] Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

plant treatment agents which are introduced into the sap conduction paths of the plants" (page 2, lines 1 – 2) not to solid dosage forms suitable for oral and rectal administration for humans and animals. Also, Tsuboi et al. do not disclose the polymeric binders required by the amended claims. Tsuboi et al. only disclose use of Biopol and Carbowax 20M. Tsuboi et al. fail to set forth each and every element as set forth in the claims. Thus, Tsuboi et al. do not anticipate the amended claims.

2. Claims 5 – 7, 11 – 12, 14, and 16 – 18 stand rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Stella et al. (US 6,046,177).

Claims 11 – 18 have been canceled.

Regarding claims 5 – 7: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."[2] Stella et al. do not disclose a weight % of cyclodextrin within the range specified in claim 8. Stella et al. do not disclose the claimed polymeric binder. Stella et al. disclose HPMC, and EMDEX, which are outside of the Markush group used to define the polymeric binder in claim 8. Thus, Stella et al. necessarily fail to set forth the solid dosage forms of claims 5 – 7, which are obtainable by a process as claimed in claim 8. Stella et al. do not anticipate the amended claims.

3. Claims 2, 8 – 10, and 13 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over Stella et al. (US 6,046,177).

Claim 13 has been canceled.

The examiner has failed to establish a *prima facie* case of obviousness, because "[t]o establish a *prima facie* case of obviousness … the prior art reference (or references when combined) must teach or suggest all the claim limitations."[3] Stella et al. do not teach or suggest a weight % of cyclodextrin within the range specified in claim 8. As discussed under point 2 above, Stella et al. do not teach or suggest the

[2] Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).
[3] MPEP §2143.

claimed polymeric binder. Thus, Stella et al. do not teach or suggest all of the claim limitations and a *prima facie* case of obviousness has not been established with regard to claim 8 as amended. "If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious."[4] Thus, claims 2, 9 and 10 are also nonobvious.

4. Claims 3 – 4 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over Stella et al. (US 6,046,177) in view of Klimesh et al. (US 4,880,585).

As admitted by the examiner, "Stella et al. do not specify the type of extruder used to shape the solid dosage form."[5] The examiner cites Klimesh et al. only to allege that "it would have been obvious to one of ordinary skill in the art …to combine the teachings of Stella et al. and Klimesh et al. and utilize a molding calendar in the extrusion process."[6] Klimesh et al. provided no teaching, suggestion or motivation to modify the disclosure of Stella et al. to compensate for the shortcomings discussed in points 2 and 3. Thus, this combination of references fails to teach or suggest all of the claim limitations and a *prima facie* case of obviousness has not been established with regard to claim 3. "If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious."[7] Thus, claim 4 is also nonobvious.

5. Claims 11, 14 – 15, and 17 stand rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Baert et al. (US 6,365,188).

Claims 11 – 18 have been canceled.

6. Claims 2 – 18 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over Baert et al. (US 6,365,188) in view of Stella et al. (US 6,046,177).

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[4] MPEP §2143.03, citing *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).
[5] Page 10, line 11 of the present Office action.
[6] Page 11, lines 1 – 3 of the present Office action.
[7] MPEP §2143.03, citing *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Claims 11 – 18 have been canceled.

Regarding claims 2 – 10: claims 2 – 7 and 9 – 10 all depend from claim 8. As discussed above, "[i]f an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious."[8] Thus, since claim 8 as amended is nonobvious over this combination of references, claims 2 – 7 and 9 – 10 are also nonobvious.

Claim 8 as amended is nonobvious over this combination of references because "[t]o establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations."[9]

Neither Baert et al. nor Stella et al. teach or suggest utilizing 0.5 to 30% by weight of at least one cyclodextrin, or 50 to 98% by weight of at least one polymeric binder selected from the group consisting of polyethylene glycol having a molecular weight above 4000, polyvinylpyrrolidone, and copolymers comprising N-vinylpyrrolidone and vinyl acetate as required by amended claim 8. Thus, this combination of references fails to teach or suggest all of the claim limitations and a *prima facie* case of obviousness has not been established. The rejection should be withdrawn.

It is noted that the examiner alleges that the process disclosed in Baert et al. "includes a) mixing the cyclodextrin with the active agent and additives, b) mixing optional additives, c) heating the mixture until melting of one of the components occurs, d) forcing the mixture through one or more nozzles, and e) cooling the mixture to obtain a solid product."[10] The examiner admits that "Baert et al. do not specify the optional additives or the weight percent of the optional additives,"[11] but

[8] MPEP §2143.03, citing *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).
[9] MPEP §2143.
[10] Page 11, lines 19 – 22 of the present Office action.
[11] Page 12, lines 6 – 7 of the present Office action.

argues that "it would have been obvious ... to combine the teachings of Baert et al. and Stella et al. and utilize the a [*sic*] polymer as the additive in Baert's process [based on the alleged motivation that] Stella teaches the use of rate controlling modifiers."[12]

This argument is in error because it fails to acknowledge the fact that Baert et al. teach away from such a combination/modification, stating that "[a]nother advantage of the present invention is that the granulation step in forming pharmaceutical, therapeutical or cosmetical compositions can be omitted, because the powdered material can simply be mixed with other excipients and compressed into, for instance, tablets or another solid pharmaceutical, therapeutical or cosmetical form .... dependent upon the other auxiliaries that are added to the unit dosage forms the unit dosage form may give immediate release or sustained release."[13] Thus, to whatever extent Baert et al. allow for rate modifying excipients, such excipients are added after the extrusion process. The rate modifying excipients are not included in the melt-extruded mixture. A person of ordinary skill in the art would, therefore, have been directed away from making the examiner's proposed combinations/modifications.

Indeed, the examiner's decision to substitute the alleged rate controlling modifiers of Stella et al. as the optional additives disclosed in the Baert et al. process seems to be based on impermissible hindsight reasoning. Without the present application as a guide, it would be impossible to derive a teaching, suggestion or motivation to combine the cited references.

It is respectfully submitted that the application is in clear condition for allowance. Favorable action is solicited.

[12] Page 13, lines 8 – 9 of the present Office action.
[13] Column 6, indicated lines 23 – 35 of Baert et al. (US 6,365,188).